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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,654	02/04/2005	Shigeru Nemoto	KITO2.005APC	1250
20995 7:	590 11/24/2006		EXAM	INER
KNOBBE MA	ARTENS OLSON &	ANDERSON, MICHAEL J		
2040 MAIN STREET FOURTEENTH FLOOR			ART UNIT	PAPER NUMBER
IRVINE, CA			3767	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office A. Communication	10/523,654	NEMOTO, SHIGERU				
Office Action Summary	Examiner	Art Unit				
	Michael J. Anderson	3767				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. (D. (35 U.S.C. § 133).				
Status		•				
1) Responsive to communication(s) filed on 02 Fe	ebruary 2006.					
	_ ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '					
3) Since this application is in condition for allowar	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.				
Disposition of Claims		•				
4)⊠ Claim(s) <u>1-8</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-8</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers						
9) The specification is objected to by the Examine	r.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
*						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) 	Paper No(s)/Mail D 5) Notice of Informal F					
Paper No(s)/Mail Date <u>02/04/2005</u> .	6) Other:	······································				

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35
 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No.
 PCT/JP03/09971, filed on 08/06/2003.

Information Disclosure Statement

- 1. The references cited in the Search Report Form PCT/ISA/210 have been considered, and will be listed on any patent resulting from this application since they were provided on a separate list in the Information Disclosure Statement (IDS) Form PTO/SB/08 in compliance with 37 CFR 1.98(a)(1). It is noted that IDS foreign patent JP3292964 A list the name of the patentee as Sugahara while the patent document submitted with the application list the inventor as Sugawara. Sugawara will be used hereafter and has been added to Form PTO-892.
- 2. The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element ("means for" in the 4th paragraph ("tubing connecting mean for connecting") and 8th paragraph ("interlock control means for interlocking") of claim 1). Please note that the MPEP clearly states,

Art Unit: 3767

"Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see MPEP 2181 (Rev. 1, Feb.2000))

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Art Unit: 3767

- 3. Claims 1, 2 3, 4, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Polaschegg (U.S. patent # 4966579) (Polaschegg). With respect to claim 1, Polaschegg discloses in figure 1, a patient tube (23), a plurality of syringe tubes (18-21), a tube connecting means (27), a syringe hold member (3-4), a plurality of syringe drive mechanisms (3-4 contains syringe infusion pumps), a plurality of tube block mechanisms (7-8), and interlock control means (17).
- 4. With respect to claim 2, Polaschegg discloses as for claim 1 above and further discloses an open or close interlock mechanism (7-8 with 17) and a block mechanism (7-8).
- 5. With respect to claim 3, Polaschegg discloses as for claim 2 above and further discloses a first press member (7), a first hold member (7), a second press (8), a second hold member (8), a press slider member supported slidably (column 4, lines 5-10, "said tubing clamping valves are mechanically actuated"; See also 35 U.S.C. 103(a) rejections) and the first press member and the second press member formed to be integral (column 4, lines 5-10, "the clamping valves and the sensors are combined in a socalled sensor and valve block"; See also 35 U.S.C. 103(a) rejections).
- 6. With respect to claim 4, Polaschegg discloses as for claim 2 above and further discloses a first press member (7), a first hold member (7), a second press (8), a second hold member (8), a press slider member supported slidably (column 4, lines 5-10 "said tubing clamping valves are mechanically actuated"; See also 35 U.S.C. 103(a) rejections), the first press member and the second press member formed to be integral

Art Unit: 3767

(column 4, lines 5-10; See also 35 U.S.C. 103(a) rejection) and supported pivotally (column 4, lines 5-10; See also 35 U.S.C. 103(a) rejection).

- 7. With respect to claim 7, Polaschegg discloses as for claim 2 above and further discloses an interlock control means (17 and column 4, lines 5-10) and syringe drive mechanism (3-4).
- 8. With respect to claim 8, Polaschegg discloses as for claim 1 above and further discloses a one-way valve (27 and 14).

Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. Claim 3 is further rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg in view of Sugawara (JP patent # 3292964) (Sugawara). Polaschegg discloses as discussed above in rejection of claim 2. With respect to claim 3, however, Polaschegg does not explicitly disclose a press slider member supported slidably and the first press member and the second press member formed to be integral. Sugawara teaches a pivotal first press member, a first hold member, a pivotal second press, a second hold member and the first press member and the second press member formed to be integral as shown in figures 5 and 6 to restrict flow from one or the other inputs.

Art Unit: 3767

Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to modify Polaschegg as taught by Sugawara in order to have a tube clamping mechanism.

- 11. Claims 4,5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg in view of Lamadrid (U.S. patent # JP 4397642) (Lamadrid).

 Polaschegg discloses as discussed above in rejection of claim 2.
- 12. With further respect to claim 4, however, Polaschegg does not explicitly disclose a first press member, a first hold member, a second press, a second hold member and the pivotal first press member and the second press member formed to be integral. Lamadrid teaches a pivotal first press member, a first hold member, a pivotal second press, a second hold member and the first press member and the second press member formed to be integral as shown in figure 2 to provide an automatic shut off. Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to modify Polaschegg as taught by Lamadrid in order to have an additional safeguard.
- 13. With respect to claim 5, however, Polaschegg does not disclose an interlock mechanism with a crank member supported pivotally on its own trailing end, a first link member for connecting a leading end of the crank member to the first press member and a second link member for connecting the leading end of the crank member to the second press member. Lamadrid teaches an interlock mechanism (Figure 2) with crank member supported pivotally on its own trailing end (22 and 83), a first link member for connecting a leading end of the crank member to the first press member (26 and 82)

Art Unit: 3767

and a second link member for connecting the leading end of the crank member to the second press member (#26 and 82) to provide an automatic shut off. Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to modify Polaschegg as taught by Lamadrid in order to have an additional patient safety mechanism.

14. With respect to claim 6, however, Polaschegg does not disclose an open or close interlock mechanism that has a cam member supported pivotally and having a concave and a convex with which the first press member and the second press member engage. Lamadrid teaches in figures 1 and 2 an open or close interlock mechanism that has a cam member supported pivotally and having a concave (26 and 82) and a convex (#28) with which the first press member and the second press member engage to provide tube occlusion. Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to modify Polaschegg as taught by Lamadrid in order to have additional safety mechanisms.

Conclusion

- 15. References considered pertinent to Applicants' disclosure are listed on form PTO-892. All references listed on form PTO-892 are cited in their entirety.
- 16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Anderson whose telephone number is (571) 272-2764. The examiner can normally be reached on M-F 7:30 am to 5:00 pm.

Art Unit: 3767

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJA 11/09/2006

> KEVIN C. SIRMONS SUPERVISORY PATENT EXAMINER

> > Levi C. kromm

Page 8